

## **REMARKS**

Claims 1-13 are pending in the application, with no claims being amended hereby. In the Final Official Action mailed May 5, 2006, Examiner rejects certain of the claims (including all of the independent claims) based on Bialecki and Barr, with the remaining dependent claims being rejected on the further basis of Luther or Bell. Applicant will focus the remarks herein on the independent claims as it is believed that they distinguish over the applied art thus rendering moot any further rejections as regards the dependent claims. As a consequence, however, for present purposes, and without waiver of the right to present further arguments as to any art and/or claims, it is submitted that resolution of the combination of Bialecki and Barr places the case in condition for allowance.

First off, it is not at all clear that Bialecki is available as prior art here. The inventors of Bialecki assigned their invention to their then-employer Ethicon Endo-Surgery, Inc. ("EES"), a subsidiary of Johnson & Johnson. EES later assigned that invention to Medex, Inc., when the latter acquired the vascular access business of EES. Mr. McGurk, the inventor on the present case, was at the time of the invention also employed by EES and, it is understood, had an obligation to assign the present invention to EES. The original application herein was filed as a provisional and prepared by an attorney at EES. At the time the application was converted, Medex, Inc. had also acquired the rights herein, and so Mr. McGurk, at the direction of EES, assigned the patent application directly to Medex, Inc.

Examiner has never indicated under what part of the statute Bialecki is being asserted as prior art. If it is based on 35 USC §102(a) in view of the publication

date thereof, Applicant would have the right to, and it is believed could, antedate same. If it is based on §102(e), then under the circumstances, 35 USC §103(e) precludes Examiner from relying on Bialecki as a reference. To that end, 35 USC §103(c) states that where a reference qualifies as prior art "only under one or more of subsections of (e), (f), or (g) of section §102", this "shall not preclude patentability" under section §103 where the reference and the presently claimed invention were, when the latter was made, "owned by the same person or subject to an obligation of assignment to the same person". That is the situation which obtains here.

Thus, if Examiner persists in the rejection, Examiner is respectfully requested to identify the section of the statute under which Bialecki is deemed to be prior art. If under §102(a), Applicant requests the opportunity to antedate the same; alternatively, if under §102(e), it is submitted that this rejection must be withdrawn (or Applicant given the opportunity to provide which other files Examiner may need to revisit that issue.)

In any event, Bialecki, as is the present invention, is directed to a protected needle catheter insertion device. In both Bialecki and the present invention, there is a needle tip protector slidably disposed in the needle. In Bialecki, the needle shaft has a crimped portion that is larger than an opening in a back wall of the needle tip protector, such that the needle cannot be pulled proximally out of the needle tip protector. Bialecki does not disclose a bent area, and so Examiner resorts to Barr. However, mere reference to Barr is insufficient to make even a *prima facie* case of obviousness.

The Examiner bears the initial burden of presenting a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if the

Examiner meets this burden does the burden shift to Applicant to come forward with evidence or an argument. Id. If examination at the initial stage does not produce a *prima facie* case of obviousness, then without more, the Applicant is entitled to grant of the patent. Id. A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claims subject matter to a person of ordinary skill in the art. In re Bell, 26 USPQ2d 1529, 153 (Fed. Cir. 1993). In this case, the teachings of the applied prior art fail to have suggested the claimed subject matter to a person of ordinary skill in the art at the time of the invention.

In that regard, it is noteworthy that Bialecki's crimp of the needle shaft already provides the mechanism to prevent proximal removal of the needle from the needle tip protector. Examiner asserts (incorrectly - more about that later) that the bent needle in Barr prevents it "from moving longitudinally within the protector 12". But, that assertion, even if correct, would not provide a basis to modify Bialecki. Indeed, Bialecki already works, and so does not present a problem in need of a solution.

It must be recognized that merely because disclosures of references might be able to be combined does not make the combination "obvious" unless the art also contains something to suggest the desirability of the combination. It is well settled that:

the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.

In re Gordon, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (emphasis added). Indeed, absent some "suggestion or incentive" from the prior art to make the modification, it is "error as a matter of law" to conclude that the claimed invention would have been obvious. ACS Hospital Systems, Inc. v. Montefiore Hospital, 221 USPQ 929, 933 (Fed. Cir. 1984).

Thus, just because the bend in the needle in Barr allegedly prevents the needle from moving within the "protector" 12, does not mean that it would have been obvious to substitute or add the bent needle to Bialecki. Indeed, why would one do so since no problem is found in Bialecki that is arguably solved thereby? The Examiner offers no reason.

In addition, it must be noted that what Examiner calls protector 12 in Barr is actually an end wall that moves with the needle, and thus is merely the support for the needle. It is by no means a protector. Indeed, Barr does not seem to care if the needle is bent or straight in terms of its operational relationship to end wall (not a protector) 12. Thus, Barr explicitly eschews the necessity for or value of a bend in the needle for such a purpose:

For example, the cannula 14 need not have an intermediate obtuse portion as shown in the drawings. The cannula may be straight or have a U-shaped intermediate portion, or have other configurations common among the known cannulae. Likewise, the outer end 18 of the cannula need not be offset with respect to the longitudinal axis of holder 10. While the outer cannula end is preferably offset to facilitate insertion into the vein of the patient, it is to be understood that the outer cannula end may also be aligned axially with holder 10.

Col. 3, ll. 13-23. Such is hardly motivation to bend the needle for purposes of its cooperation with the needle tip protector.

By contrast, the needle tip protector of Bialecki operates by arms that bear against the needle shaft, and then close down over the tip as it passes between the arms. There is nothing in Barr that even remotely suggests that a bend in the needle shaft to create offset, but generally parallel, sections of the needle as claimed herein would have been expected to work in such a needle tip protector. It is Applicant who made that

discovery, not the prior art. It appears Examiner has simply used Applicant's claims as a blueprint to abstract bits and pieces of the prior art together, through hindsight to make the above §103 rejection. This is error as a matter of law. W.L. Gore & Associates, Inc. v. Garlock Inc., 220 USPQ 303, 312 (Fed. Cir. 1983). It must be recognized that a combination of prior art is improper and not "obvious" if the only suggestion or reason for combining the teachings of the prior art is to be found in the present application. In re Pye & Peterson, 148 USPQ 426 (CCPA 1966). Nothing about Barr suggests its application to Bialecki, nor is there any reason, suggestion, or motivation to modify the Bialecki needle merely to allegedly achieve what Bialecki already achieves.

To properly combine references to make a prima facie case of obviousness, case law requires that there must have been some teaching, suggestion or inference in either one of the references, or both, or knowledge generally available to one of ordinary skill in the relevant art, which would have led one skilled in the art to combine the relevant teachings of the two references. See, e.g., ACS Hospital Systems, supra, 221 USPQ at 933; W.L. Gore & Associates, supra, 220 USPQ at 311; and In re Dembiczak, 50 USPQ2d 1614, (Fed. Cir. 1999). There is nothing of the sort here such that the §103 rejections of the independent claims fail.

Because the independent claims are patentable, as explained above, the dependent claims are likewise patentable for at least those same reasons. Applicant will thus not address the dependent claims at this time so as to streamline prosecution, but reserves the right to address such claims if necessary.

## **Conclusion**

In view of the foregoing, Applicant respectfully solicits reconsideration and withdrawal of the §103 rejections. Applicant submits that all outstanding issues in the Official Action have been addressed, and that the pending claims are in condition for allowance. Applicant therefore solicits a formal Notice of Allowance at the earliest opportunity. If any issues remain, Examiner is respectfully asked to telephone undersigned attorney in an effort to promptly resolve same.

No fee is believed due for this filing. If any fee is due, consider this as an authorization to charge deposit account 23-3000 therefor.

Respectfully submitted,

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